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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,698

06/13/2006

Eli Ryssdal Andersen

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GE HEALTHCARE, INC.
IP DEPARTMENT
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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,698	Applicant(s) ANDERSEN ET AL.	
	Examiner Melissa Perreira	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-11 and 13-15 is/are rejected.
- 7) ☐ Claim(s) 2-5,12 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/25/07 has been entered.

Previous Rejections and Claims Status

2. Claims 1-15 are pending in the application. Claim 17 is withdrawn from further consideration.
3. The rejection of claims 1,6,10,11,13 and 14 under 35 U.S.C. 102(b) as being anticipated by deLearie et al. (US 5,508,388) is maintained.
4. The rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Dazzi (US 3,660,388), Wagner et al. (US 4,698,263), Gibby (US 4,822,594) and deLearie et al. (US 5,508,388) are withdrawn. Applicant's assertions are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,6,10,11,13,14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by deLearie et al. (US 5,508,388).
7. deLearie et al. (US 5,508,388) teaches of the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine in the molar ratio of 1.0:3.0:4.5 respectively at various temperatures between 55°C to 74°C for 18-22h without acetonitrile (column 6, example 2).

Response to Arguments

8. Applicant's arguments filed 10/25/07 have been fully considered but they are not persuasive.
9. Applicant asserts that deLearie et al. uses acetonitrile in the reaction to reduce the amount of pyridine while the instant invention does not utilize acetonitrile.
10. deLearie et al. discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine in the molar ratio of 1.0:3.0:4.5 respectively at various temperatures between 55°C to 74°C for 18-22h without acetonitrile (column 6, example 2). Also, deLearie et al. states that pyridine is highly toxic and relatively expensive, therefore the amount of pyridine used in the process is reduced to the minimum required to form the desired bis(anhydride) (column 3, lines 24-27).

New Grounds of Rejection

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1,6-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dazzi (US 3,660,388) in view of deLearie et al. (US 5,508,388).

13. Dazzi (US 3,660,388) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid (6 eq) and pyridine (6.5 eq) at 60°C for 48h (column 6, example 9) without the use of acetonitrile. The reaction of the tetracarboxylic acids of the disclosure is advantageously performed between room temperature and below the decomposition point of the tetracarboxylic acids (i.e. 10°C up to about 150°C), in excess of the monocarboxylic acid anhydride (i.e. acetic anhydride) and the presence of a tertiary nitrogen base (i.e. pyridine) (column 1, lines 45-55; column 2, lines 68+; column 3, lines 1-8). Dazzi does not disclose less than 6.5 equivalents of pyridine.

14. deLearie et al. (US 5,508,388) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine in the molar ratio of 1.0:3.0:4.5 respectively at various temperatures between 55°C to 74°C for 18-22h without acetonitrile (column 6, example 2).

15. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize acetic anhydride and pyridine for the process for the production of DTPA-bis(anhydride) without the use of acetonitrile. Dazzi discloses that pyridine is a particularly active base that accelerates the reaction and improves the yields while deLearie et al. discloses that by minimizing the amount of pyridine (to 4.5 eq) in the reaction mixture, the amount of time necessary for the reaction can be reduced from 48 h (Dazzi) to 18-22 h. Also, pyridine is highly toxic and relatively expensive, therefore the amount of pyridine used in the process is reduced to the minimum required to form the desired bis(anhydride) (deLearie et al. column 3, lines 24-27). Therefore it would be obvious to reduce the amount of pyridine to reduce toxicity while also reducing the reaction time without the use of acetonitrile.

16. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

17. Claims 1,6-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibby (US 4,822,594) in view of deLearie et al. (US 5,508,388).

18. Gibby (US 4,822,594) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with a molar amount of acetic acid four times that of DTPA and a molar amount of pyridine that is six times the amount of DTPA at 65°C for 20h (column 4, example 1) without the use of acetonitrile. The reaction mixture can also be heated from 45°C to about 85°C (column 3, lines 52-61). Gibby does not disclose less than 6.0 equivalents of pyridine.

19. deLearie et al. (US 5,508,388) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid and pyridine in the molar ratio of 1.0:3.0:4.5 respectively at various temperatures between 55°C to 74°C for 18-22h without acetonitrile (column 6, example 2).

20. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize acetic anhydride and pyridine for the process for the production of DTPA-bis(anhydride) without acetonitrile. deLearie et al. discloses that by minimizing the amount of pyridine (to 4.5 eq) in the reaction mixture, the amount of time necessary for the reaction can be reduced from 20 h (Dazzi) to 18 h. Also, pyridine is highly toxic and relatively expensive, therefore the amount of pyridine used in the process is reduced to the minimum required to form the desired bis(anhydride) (deLearie et al. column 3, lines 24-27). Therefore it would be obvious to reduce the amount of pyridine to reduce toxicity while also reducing the reaction time without the use of acetonitrile.

21. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios,

concentrations, percentages, etc.). It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

No claims are allowed at this time. The instant claims 2-5,12 and 16 are objected to for depending on a rejected base claim but are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/Melissa Perreira/
Examiner, Art Unit 1618

February 9, 2008